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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,723

10/17/2006

Makoto Kigoshi

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02/02/2009

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,723	<b>Applicant(s)</b> KIGOSHI ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-4, 10 and 11 is/are pending in the application.  
     4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

Applicant's response of November 24, 2008, to the Restriction Requirement dated October 22, 2008 has been entered. Claims 1 and 4 have been amended, and claims 5-9 cancelled. No claims were newly added. Accordingly, claims 1-4, 10 and 11 are pending in the application.

***Election/Restrictions***

Applicants' election of Group I (claims 1-10), drawn to a method of producing coated fine particles in which core fine particles are coated with a coating layer, which comprises the step of mixing a liquid A containing a polar organic solvent in which core fine particles are dispersed and a coating layer component constituting the coating layer is dissolved; with a liquid B which is miscible with the liquid A and does not contain a polar organic solvent; thereby coating the core fine particles with a coating layer, is acknowledged. The election was made without traverse. Applicants' election for the species of lipid membrane components as the coating layer, a complex of drug and liposome as the core fine particle and alcohols as the polar organic solvent (also without traverse), is further acknowledged.

Claim 11 is hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

As the restriction is still deemed proper, the requirement for restriction is maintained and hereby made FINAL. The instant claims have been examined commensurate with the scope of the elected invention and the species of the elected invention. Applicants timely responded to the restriction (election) requirement in the reply filed November 24, 2008.

Elected claims 1-4 and 10 are under current examination.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on February 19, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner, and indicated as such on Applicants' IDS form.

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***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in JAPAN on 03/23/2004. It is noted, however, that applicant has not filed a certified copy of the 2004-084216 NO application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Leclef et al. (U.S. Patent No.: 5,100,591; Mar. 31, 1992), in view of Chen et al. (U.S. Patent No.: 6,537,813; filed Feb. 16, 1999).

The claims encompass a method of producing fine particles coated with a lipid membrane, said particles containing a complex of drug and liposome, which comprises the step of mixing a liquid A containing a polar organic solvent (alcohol) in which core fine particles are dispersed and a lipid membrane are dissolved; with a liquid B which is miscible with the liquid A and does not contain a polar organic solvent.

Leclef et al. describe a process for preparing lipid microparticles possessing an affinity for phospholipids, wherein the water-insoluble microparticles and the phospholipid are dissolved in a common organic solvent, and the solution is subsequently mixed with an aqueous solution in an amount such that an insolubilization takes place in the form of a precipitate, and the organic

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solution is removed to recover an aqueous solution containing the microparticles in the form of a microsuspension (Title and Abstract). Leclef et al. specifically exemplify the preparation of a microparticle of phosphatidylcholine and the drug amphotericin B, in Example 1 (column 5), and state that compared to the preparation of liposomes and microparticles according to an earlier process, their process is simpler and more economical (column 2, lines 25-27). Leclef et al. additionally describe polar organic solvents such as methanol and ethanol as specific examples of organic substances that may be utilized in their process, and water or saline solutions such as phosphate buffer as aqueous solutions (column 2, lines 47-55; limitations of claims 1 and 10).

While Leclef et al. do not describe mixing the two solutions via a device equipped with a mixing means, such was known in the prior art.

Chen et al. describe concurrent flow mixing methods and apparatuses for the preparation of gene therapeutic compositions, relating to making mixtures and condensate compositions via controlled and uniform mixing of various compositions (Title and Abstract). Chen et al. specifically describe an apparatus comprising a first and second solutions introduction means connected to a mixing means having two inlets and one outlet, connected to a flow controller (Figure 1), and an apparatus wherein flow is controlled via a syringe (i.e. a manual pump; Figure 3, limitation of claim 3). Controllable pumps are further described in column 26, lines 14 and 50. Figures 1 and 3 each shows the structures of a pump, a flow path and an in-line mixing means (limitation of claim 2). Chen et al. further describe condensing agents for use in the apparatuses, that include liposomes, emulsions and microemulsions (column 17, lines 8-9), as well as matrix formulations such as microparticles (column 13, line 26).

The teachings of Leclef et al. and Chen et al. encompass the production of therapeutic compositions that include lipids and microparticles. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art, to combine their respective teachings and to produce the coated microparticles of Leclef et al. using the apparatus of Chen et al., as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would have been motivated to mix liquids A and B using the mixing means of Chen et al., because such was expressly taught by Chen et al. and would further allow for industrial scale applications (paragraphs 25 and 26 of Chen et al.).

***Conclusion***

**Claims 1-4 and 10 are not allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/  
Examiner, Art Unit 1633